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Original Research Article

A study on adverse events following immunisation among COVID-19 vaccine recipients at a tertiary care hospital in Kashmir valley

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ABSTRACT

Background: Adverse events following immunization (AEFI) is an event of unexpected medical emergency occurring after vaccination without any causal association with vaccination. It can be any unintended, abnormal laboratory finding or anything. The present study was conducted to evaluate the incidence and severity of AEFI associated with the COVID-19 vaccines.
Methods: All the beneficiaries who had received two doses of Covishield and Covaxin vaccine from SKIMS Soura and provided consent were included in this prospective study. Each beneficiary was contacted telephonically. A self-designed questionnaire was used to interview them. The beneficiaries were contacted twice. The data was entered into and analysed using SPSS version 20.
Results: A total of 267 participants (52.3%) reported at least one of the AEFI following Covaxin vaccine. It was found that participants with AEFIs following the first dose had more chances to develop them following its second dose and this difference was found to be statistically significant (OR=6.8, p=0.0001). A total of 670 participants (38.0%) reported at least one of the AEFI following Covishield vaccine. The incidence of AEFIs was more after the first dose (31.6%) than that of the second dose (6.4%) and this difference was found to be statistically significant (p<0.0001).
Conclusions: Most of the AEFI are minor and can be managed symptomatically. Therefore, these AEFIs should not be a hurdle for vaccination.

Keywords: Immunisation, Adverse events, COVID, Vaccination, Side effects

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection started in Wuhan, China in December 2019 and since then has spread worldwide. The infection has not been fully controlled yet. As of august 31, 2022, more than 599 million of infection cases and 6.5 million related deaths were confirmed.[1] As there is no specific treatment available for COVID-19, preventive measures like COVID-appropriate behaviour and vaccines remain the mainstay of protection. During the pandemic, vaccines against COVID-19 were developed at an unprecedented speed. These vaccines had a different level of effectiveness and were approved for emergency use. In India, five vaccines have been approved by the drugs controller general of India to date. Vaccines approved in India are Covishield (ChAdOx1), COVID-19 vaccine (Covaxin) (BBV152), Sputnik V, Johnson and Johnson, and Zycov-D.[2-4] In India, the COVID-19 vaccination was initiated on January 16, 2021 with two COVID-19 vaccine candidates (Covishield and Covaxin) approved by the country's drug controller.[3] However, several adverse events associated with COVID-19 vaccines have been reported in India.

AEFI is basically an event of unexpected medical emergency occurring after vaccination without any causal association with vaccination. It can be any unintended, abnormal laboratory finding or anything. At the time of vaccination, there are many reasons like improper way of vaccination by health worker or quality defect of any specific vaccine. All these are the unintentional events which can lead to an adverse event in any individual. There have been few studies related to AEFI after COVID-19 vaccination in Kashmir division. So, the present study was conducted to evaluate the incidence and severity of AEFI associated with the COVID-19 vaccines.

METHODS

In India, the COVID-19 vaccination was initiated on January 16, 2021 with two covid-19 vaccine candidates (Covishield and Covaxin) approved by the country's drug controller. These vaccines were also started from the same time period in the health facility of SKIMS. In this regard, a prospective type of study was conducted by our department for a period of one year from February 2021 to January 2022. All the beneficiaries who had received two doses of Covishield and Covaxin vaccine from SKIMS Soura and provided consent were included in the study. The list of the beneficiaries was obtained from records maintained at the vaccination booths at SKIMS. Beneficiaries enrolled in the list of recipients of vaccine were selected by simple random sampling technique using random number tables and these were contacted telephonically and consent was obtained from them for being a participant of the study. During our one-year study period, a total of 2574 was included. Among them,1984 had received Covishield and 590 had received Covaxin. Once they provide consent, the information was collected using a self- designed questionnaire which included information pertaining to sociodemographic characteristics, vaccination details and details of any observed AEFI associated with COVID-19 vaccine. The beneficiaries were contacted twice; first within 1 week to 1 month after 1st vaccine dose and second within 1 week to 1 month after receiving 2nd dose of the COVID-19 vaccine.

Exclusion criteria

Those recipients who did not respond to three phone calls were excluded from the study.

Statistical analysis

The data was entered into and analysed using IBM SPSS version 20. The statistical tests were applied based on the type of variable and normality of the data.

Ethical approval

Ethical approval was sorted from the SKIMS IEC committee.

RESULTS

In our study, a total of 590 participants were interviewed following Covaxin vaccination, however out of them 510 responded to our calls with a non-response rate of 13.6%. Majority of the participants (79.0%) belonged to the age group of 21-40 years. There was a male preponderance (66.5%). 65.9% of the participants were graduates and post graduates and 30.0% were students by occupation. Only 4.5% of the study participants had any comorbidity. Only 6.3% had known history of allergy to any kind of food, drug or other allergens. 15.5% had history of prior covid-19 infection (Table 1).

A total of 267 participants (52.3%) reported at least one of the AEFI during our study. All AEFI reported were minor which were managed symptomatically and subsided after 1-2 days. The incidence of AEFIs was more after the first dose (28.4%) than after the second dose (23.9%). However, the difference in incidence was not statistically significant (p=0.1022). Furthermore, the association between adverse events following immunization and other demographic variables was not found to be the statistically significant (p>0.05) (Figure 1).

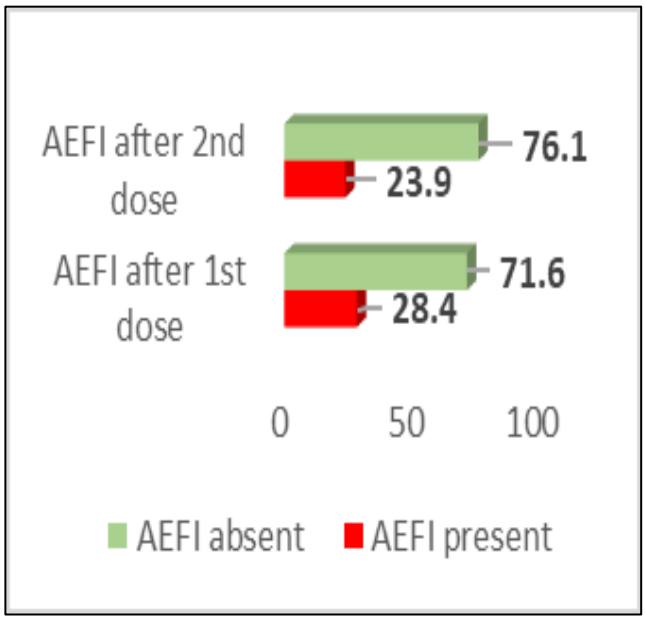

Figure 1: Frequency of AEFI among Covaxin immunized population (n=510).

It was found that participants with AEFIs following the first dose had more chances to develop them following its second dose and this difference was found to be statistically significant (OR=6.8, p value of 0.0001) (Table 2).

A total of 367 adverse events were reported following two doses of Covaxin. The most common adverse events were fever, body ache, pain at injection site, weakness and headache. The fewer common adverse events were

heaviness in arm, giddiness, headache and other less common mild AEFI (Table 3).

A total of 1984 were interviewed following Covishield vaccination, however out of them 1762 responded to our calls with a non-response rate of 11.2%. More than half of the participants (56.6%) belonged to the age group of 41-60 years. Male participants (59.6%) were more than that of female participants (40.4%). 32.3% of the participants were graduates and post graduates and 20.0% were professionals. HCWs/FLWs constituted 25.8% of our study participants. Comorbidities were present in 37.3% of the participants which were mostly in the form of hypertension and diabetes. Only 4.3% had known history of allergy to any kind of food, drug or other allergens. 11.5% had prior COVID-19 infection (Table 4).

Table 1: General characteristics of the study population receiving Covaxin, (n=510).

Characteristics		Total	Percent (%)
Age (years)	<20	47	9.2
	21-30	236	46.3
	31-40	167	32.7
	41-50	54	10.6
	51-60	6	1.2
Gender	Male	339	66.5
	Female	171	33.5
Education	Illiterate	13	2.5
	Primary	2	0.4
	Middle	7	1.4
	Secondary	23	4.5
	Higher sec/ diploma	58	11.4
	Graduate	210	41.2
	Postgraduate	126	24.7
	Professional	71	13.9
Occupation	Unemployed/ home maker	79	15.5
	Student	153	30.0
	Professional	47	9.2
	Paramedical staff	7	1.4
	Supportive staff	3	0.6
	Govt. employees	73	14.3
	Self-employed/ business	148	29.0
Comorbidity	Yes	23	4.5
	No	487	95.5
History of allergy	Yes	32	6.3
	No	478	93.7
Prior COVID-19 infection	Yes	79	15.5
	No	431	84.5

Table 2: Association of AEFIs following two doses of Covaxin.

AEFI 1st dose	AEFI 2nd dose, N (%)		Total, N (%)	Odds ratio (95% CI)	P value
	Present	Absent			
Present	74 (51)	71 (49)	145 (100)	6.8 (4.4-10.7)	0.0001
Absent	48 (13.2)	317 (86.8)	365 (100)		
Total	122 (23.9)	388 (76.1)	510 (100)		

Table 3: Types of AEFI reported among the study participants.

Type of AEFI	I st Dose (n=207)		2nd Dose (n=160)	
	N	%	N	%
Fever	64	12.5	39	7.7
Bodyache/ myalgias	58	11.4	39	7.6
Pain at injection site	25	4.9	12	2.4
Weakness	20	3.9	22	4.3
Headache	12	2.4	14	2.7
Heaviness arm	9	1.8	16	3.1
Giddiness	7	1.4	5	1
Nausea	4	0.8	5	1
Rash	3	0.6	1	0.2
Malaise	3	0.6	1	0.2
Rhinitis	1	0.2	1	0.2
Itching	1	0.2	0	0
Breathlessness	1	0.2	0	0
Chills	0	0	4	0.8
Vomiting	0	0	1	0.2

A total of 670 participants (38.0%) reported at least one of the Adverse events following immunization during our study. The incidence of AEFIs was more after the first dose (31.6%) than that of the second dose (6.4%) and this difference was found to be statistically significant ($p<0.0001$) (Table 5).

Majority of the participants (92%) reported minor Adverse events following immunization which were managed symptomatically and subsided after one to two days. The severe adverse events were reported in 8% participants which were mostly high-grade fever and hypertension. However, no serious adverse events were reported during our study period. A total of nine hundred and ninety-nine adverse events were reported following two doses of Covishield. The most common adverse events were fever and Bodyache/ myalgias. The less common adverse events were pain at injection site, malaise, headache, chills, weakness, hypertension, etc. (Figure 2) (Table 6).

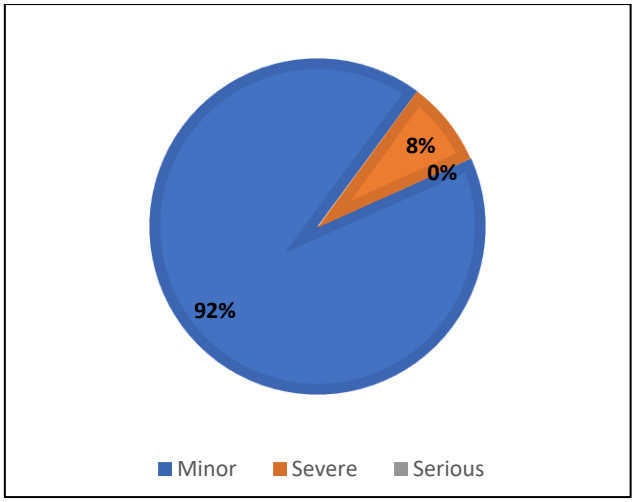

Figure 2: Nature of AEFIs following the two doses of Covishield vaccine.

Table 4: General characteristics of the study population receiving Covishield, (n=1762).

Characteristics	N	Percent (%)
Age (years)		
21-30	130	7.4
31-40	143	8.2
41-50	435	24.6
51-60	564	32.0
61-70	345	19.6
>70	145	8.2
Gender		
Male	1051	59.6
Female	711	40.4
Educational qualification		
Illiterate	340	19.3
Primary	05	0.3
Middle	102	5.8
Secondary	172	9.8
Higher secondary/diploma	222	12.6
Graduate/ post graduate	569	32.3
Professional	352	20.0
Occupational status		
Unemployed/home maker	451	25.6
Student	45	2.6
HCWs/FLWs	455	25.8
Govt. employees	490	27.8
Self-employed/ businessmen	321	18.2
History of allergy		
Yes	76	4.3
No	1686	95.7
Co-morbidity status		
Yes	658	37.3
No	1104	62.7
Prior COVID-19 infection		
Yes	202	11.5
No	1560	88.5

Table 5: Frequency of AEFI among Covishield immunized population, (n=1762).

AEFI status	1st dose, N (%)	2nd dose, N (%)	P value
Yes	557 (31.6)	113 (6.4)	<0.0001
No	1205 (68.4)	1649 (93.6)	

Table 6: Types of AEFI reported among the study participants.

Type of AEFI	1st dose, (n=825)		2nd dose, (n=166)	
	N	%	N	%
Fever	323	18.3	38	2.1
Body ache/ myalgias	211	11.9	32	1.8
Pain at injection site	50	2.8	8	0.4
Malaise	46	2.6	9	0.5
Headache	43	2.4	13	0.7
Chills	41	2.3	9	0.5
Weakness	38	2.2	9	0.5
Nausea/ vomiting	6	0.3	0	0
Heaviness in arm	23	1.3	3	0.2
Giddiness	19	1.1	14	0.8
Hypertension	11	0.6	3	0.2
Loose motion	8	0.5	0	0
Rhinitis	6	0.	2	0.1

DISCUSSION

Surveillance for AEFI after vaccination is an important public health intervention as fear of AEFIs is one of the primary reasons for vaccine hesitancy.[5,6] Detection and quantification of mild adverse events are usually missed by passive surveillance. Safety of product is of paramount importance and in this study, we actively captured adverse events postvaccination. It is important for people to be aware of the minor side effects which are manageable with some symptomatic treatment like paracetamol to resolve the symptoms timely and to increase the acceptance of the COVID-19 vaccine among the mass population while decreasing the psychological fear of any side effect of vaccination. Vaccines have side effects but they are not as severe as the disease for which that vaccine is prepared.

In our study, we have investigated AEFI among both Covaxin and Covishield beneficiaries. A total of 510 participants received Covaxin and 1762 received Covishield vaccine. Among Covaxin recipients, majority of the participants (79.0%) belonged to the age group of 21-40 years with male predominance (66.5%) as initially Covaxin was started in the same age group. Only 4.5% of the study participants had any of the comorbidities, 6.3% with known history of allergy and 15.5% had prior COVID-19 infection. Among Covishield recipients,

majority of the participants (76.2%) belonged to the age group of 41-70 years with male preponderance (59.6%). HCWs/ FLWs constituted 25.8% of our study participants because Covishield was initially prioritised in them only. 37.3% of the participants had comorbidities, 4.3% had known history of allergy and 11.5% had prior covid-19 infection. The number of subjects who reported Adverse events was 267 following two doses of Covaxin and 670 following Covishield. The incidence rate of AEs following COVAXIN was 52.3% and following COVISHIELD™ was 38.0%. In case of Covaxin, the incidence of AEFIs was more after the first dose (28.4%) than that of the second dose (23.9%). This finding was similar to a study done by Parida et al.[7] However, the difference in incidence was not significant statistically (p=0.102). It was found that participants with AEFIs following the first dose had more chances to develop them following its second dose and this difference was statistically significant (OR=6.8, p=0.0001). A total of 367 adverse events were reported following two doses of Covaxin. Out of them, 207 were reported with the first dose,160 with the second dose of Covaxin. All AEFI reported were minor which were given symptomatic management and subsided after 1-2 days. The most common adverse events were fever (102), bodyache (97), weakness (42), pain at injection site (37), and headache (26). The fewer common adverse events were heaviness in arm, giddiness, headache and other less common mild AEFI. In case of Covishield, the incidence of AEFIs was more after the first dose (31.6%) than that of the second dose (6.4%) and this difference was found to be statistically significant (p<0.0001). These findings are in consistent with studies conducted by Kamal et al and Menni et al.[8,9] A total of 991 adverse events were reported following two doses of Covishield. As per the nature of AEFI is concerned, majority of the participants (92%) reported minor AEFI which were given symptomatic management and consequently subsided after 1-2 days. The severe adverse events were reported in 8% which were mostly high-grade fever and hypertension. However, no serious adverse events were reported during our study period. The most common adverse events were fever (361), myalgia (243), pain at injection site (58), headache (56), malaise (55). Other less common events were chills, weakness, vomiting, heaviness in arm, etc. Furthermore, hypertension was reported by 14 recipients.

Limitations

As the beneficiaries were interviewed telephonically, we had to rely on the patients' complaints while we could not confirm the same. For example, we could not check the body temperature but relied on the patients' complaint of having fever following the vaccination. In addition, we included the beneficiaries who received vaccines from this institute while those who received it from other centres could not be interviewed for the symptoms. So, our study may have missed some adverse events.

CONCLUSION

Reporting of adverse events is important to combat vaccine hesitancy among public. In our study, active reporting was done telephonically. Most of the adverse events reported during our study period were minor and need symptomatic management only. Therefore, these adverse events should not be hurdle for vaccination.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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